"Judgment is ordered entered for the plaintiff as prayed for in its complaint, restraining and enjoining the defendants, their servants, agents, officers, employees, attorneys and assigns, and each of them, from the introduction or delivery for introduction into interstate commerce of any of their said products herein before designated and described as 'Sekov', 'Sekov Reducer', 'Sekov Reducer for Men', 'Sekov Formula P', 'Sekov Formula R', and 'Sekov Formula T,' in violation of or contrary to Title 21, U. S. C. A., Sections 301 to 392.

"I am of the view that the evidence shows clearly that the preparation is misbranded because 'it is dangerous to health when used in the dosage or with the frequency or duration prescribed and recommended or suggested in the label thereof.' (21 U. S. C. A. Sec. 352 (j).) Even the physicians who testified for the defendants admitted that the use of thyroid extracts in the quantity prescribed by obese persons, whose obesity *was not due* to hypothyroidism, might prove injurious to health. The physicians who testified for the Government, each of whom is an expert in his field, were emphatic in their statement that such use not only might be detrimental, but in all likelihood would be so. If the defendants limited sales to persons who are suffering from obesity due to hypothyroidism,—either by requiring a physician's certificate to that effect, or by conducting an examination of the person before making a sale, it could well be contended that, with such precaution, any detrimental results would be only those incident upon any selfmedication, which the law does not prohibit. As the sale is not made through general outlets, but through agencies conducted by the defendants—studios located in various cities throughout the United States, such safeguards could easily be enforced. As it is, the record shows that any obese person who calls at one of these studios can obtain the product without any inquiry as to whether the conditions for which the product is intended as a remedy, co-existing obesity and hypothyroidism,—are present. In view of this, the statement on the carton that the preparation is 'a reducer for overweight due to a thyroid deficiency' and similar statements in the pamphlet are inadequate to forestall the evil inherent in the use of this preparation by persons whose hypothyroidism has not been established by a competent physician. It is to be noted, as stated by me during the argument, that nowhere is there a warning couched in imperative negatives such as are found in products which may have a deleterious effect. Nowhere is there a statement '*Do not use this* unless a physician has told you that your obesity is due to hypothyroidism'. The reference to the consultation of a physician is ineffective. It reads: 'We recommend that you consult physician to determine the cause of your overweight as the use of THYROID by a person not deficient in THYROID may result in serious or irreparable injury to the health of the user'.

"I am also satisfied that the contra-indications are inadequate. In the light of the expert testimony, I do not think that the average person seeking to reduce would be competent to detect the evils resulting from its use. Bearing in mind that the defendants in their advertising and literature, appeal especially to the vanity of women, I am of the view that the average woman, in her desire to achieve a beauty of form, would be more inclined to consider the manifestations of ill effect as the natural price to pay for the results to be achieved. So that if we consider the warnings in relation to the persons to whom they are addressed, as counsel bids us to, it is quite evident that they are ineffective for the purpose."

On June 25, 1943, the court handed down findings of fact substantially sustaining the allegations in the complaint, and conclusions of law sustaining the prayer of the complaint. On the same day a decree for permanent injunction was filed, ordering the defendants forever restrained and enjoined from introducing or delivering for introduction into interstate commerce any of their products designated and described as "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T."

1002. Misbranding of Sekov Reducer. U. S. v. 15 Cartons of Sekov Reducer. Tried to the court without a jury. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 5167. Sample No. 11274–E.)

Misbranding of Sekov and adulteration and misbranding of Sekov Formula "P." U. S. v. 47 Cartons and 6 Cartons of Sekov and 7 Cartons of Sekov Formula "P." Default decrees of condemnation and destruction. (F. D. C. Nos. 7992, 7993, 9500. Sample Nos. 11077–E, 11078–E, 11056–F.)

On July 21, 1941, July 29, 1942, and March 6, 1943, the United States attorneys for the Southern District of Texas and the District of Nevada filed libels against 62 cartons of a product labeled "Sekov," or "Sekov Reducer," and 7 cartons of Sekov Formula "P" at Houston, Tex., and 6 cartons of Sekov at Reno, Nev., al-

leging that the articles had been shipped in interstate commerce within the period from on or about May 24, 1941, to January 8, 1943, by the Sekov Corporation or Sekov Studio, from Hollywood, Calif.; and charging that they were misbranded and that the Sekov Formula "P" was also adulterated.

Examination showed that each carton of the Sekov, or Sekov Reducer, contained two types of capsules, "No. 1" and "No. 2," respectively. Analyses of samples showed that the "No. 1" capsules consisted of glandular material including thyroid in amounts ranging from 1.84 grains to 1.95 grains per capsule; that the "No. 2" capsules contained rhubarb root, cascara sagrada bark, aloin, and asafetida; and that the Formula "P" contained approximately 1.73 grains of thyroid per capsule.

The products were alleged to be misbranded (1) in that the labeling was false and misleading; (2) in that the articles were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling; and (3) (portions) in that their labelings failed to bear adequate directions for use, and such adequate warnings as are necessary in case of thyroid and laxative preparations. (The misbranding charges are more fully set forth in the opinion of the court below.)

The Formula "P" was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented to contain "Active Ingredients Thyroid, U. S. P. 1 Gr.," whereas it contained more than 1 grain of U. S. P. thyroid per tablet.

The Sekov Corporation of Los Angeles, Calif., filed its claim and answer in the Southern District of Texas to the libel involving 15 cases of "Sekov Reducer," and filed a motion for removal of the case to the Southern District of California. On September 18, 1941, the court denied this motion, handing down the following opinion:

KENNERLY, *District Judge*:

"This is a suit by the United States of America to condemn under the Federal Food, Drug and Cosmetic Act of June 25, 1938 (Title 21, Sections 301 to 392, U. S. C. A.), Fifteen Cartons, more or less, of articles called 'Sekov Reducer.' Such articles were at the time of the filing of said suit, and are now, situated in the City of Houston in this Division and District. They have been seized by the Marshal. His Return shows that they were in possession of Sekov Reducing Studio when seized.

"Sekov Corporation, a claimant of such articles (for convenience called Claimant), has filed a Motion to transfer the suit to the District Court of the United States in the District in which Claimant says it has its principal place of business, i. e., Hollywood, in the Southern District of California. This is a hearing on such Motion under Local District Court Rule 25. The matter is to be determined from the pleadings of the parties which for the purpose of this hearing will be regarded as stating the facts.

"1:—The particular provision of such Act upon which Claimant relies to support such Motion is the following portion of Section 334, Title 21, U. S. C. A.:— 'In any case where the number of libel for condemnation proceedings *is limited* as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.'

"The Government answers the Motion with the claim that in this case the number of libel for condemnation proceedings *is not limited* under that portion of Section 334 which reads as follows:—

'(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 344 or 355, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such

proceeding is so pending, except that such limitations shall not apply:— * * *
'(2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.'

"I think the Government is right, and that this is not a case that may be transferred.

"2:—It will be observed also from Section 334 that a claimant such as is the Claimant here is not necessarily entitled to have the case transferred to the District in which it has its place of business, but only a District of 'reasonably proximity' thereto. But that such transfer shall take place unless good cause to the contrary is shown.

"Not only is this a case where proceedings are not limited, but good cause is shown why it should not be transferred. It not only appears that the articles are situated in this District, but were in the hands of a person other than claimant when seized and that many of the witnesses are in this District.

"Claimant's motion will be denied. Let an Order be prepared and presented accordingly."

On April 13, 1942, the case against the 15 cartons at Houston, Tex., came on for trial before the court, and on April 30, 1942, the court found all issues of fact and law for the Government, handing down the following opinion:

KENNERLY, *District Judge*:

"This is a libel by the United States Government under the Federal Food, Drug and Cosmetic act (Sections 301 to 392, Title 21, U.S. C. A.), to condemn Fifteen Cartons, more or less, of Sekov Reducer, a claimed remedy for obesity, found and situated in this District and Division, alleged to be misbranded within the meaning of the Act, and to have been shipped on or about May 24, 1941, in Interstate Commerce by Sekov Corporation, Hollywood, California, to Sekov Reducing Studio, Houston, Texas, for sale by such Studio. The Sekov Corporation (for brevity called Claimant) is here, claiming such articles, denying the allegations of the Government, and contending for immunity here because, as it says, the Federal Trade Commission in a proceeding before it has heretofore assumed jurisdiction of and decided the questions here involved.

"It has been stipulated that the articles sought to be condemned were shipped in Interstate Commerce for sale in this District and Division as alleged, that they have been seized, and the Complaint and Order in the proceedings before the Federal Trade Commission are in evidence. Thus we are brought at once to the questions to be determined.

"1:—The Government complains with respect to such articles as follows:—'Said article is misbranded in violation of the Act of June 25, 1938, known as the Food, Drug and Cosmetic Act, in that the statement on the carton 'Reducer' and the design of a slender female figure are false and misleading, since they imply that the article is a safe and appropriate treatment for the reduction of weight, when in fact the article is not such a safe and appropriate treatment but is a dangerous drug and does not constitute an effective agent in reducing weight.'

"This complaint is bottomed on that part of the Act reading as follows (Section 352 (a), Title 21, U.S. C. A.):—'A drug or device shall be deemed to be misbranded: * * * If its labeling is false or misleading in any particular.'

"On the outside of the container or package of 'SEKOV' are these words:—'SEKOV Trade Mark Reg. U. S. Pat. Off. REDUCER (Then follows a picture of a woman with a slender figure) Manufactured for—Packed by 6404 Hollywood Blvd—Sekov Corporation—Hollywood, California.'

"'Sekov' comes in and is to be taken in two capsules, stated on the label to contain and which the evidence shows do contain ingredients as follows:—'No. 1 Capsule Active Ingredients Thyroid, U. S. P. 1.87 Gr. Whole Ovarian Whole Pituitary Aloin No. 2 Capsule Active Ingredients Rhubarb Powder Asafetida Cascara Sagrada Oleoresin Ginger Aloin-Bile Salts.'

"I find the labeling false and misleading. The evidence clearly shows that 'Sekov' is not a reducer, i. e., that it is not a remedy for obesity and will not reduce the weight or figure of a heavy or stout woman to the slender proportions shown in the picture on the container.

"It is shown that the Sekov Reducing Studio, Houston, was furnished by Claimant with a supply of printed booklets, the title of which is 'Sekov, A Path to Slenderness'. These booklets were shipped to the studio in Interstate Commerce and kept on hand by the Studio in Houston and sent or delivered to persons making inquiry by mail or in person with respect to 'Sekov'. The evidence is not

convincing that one of these booklets went to every purchaser of 'Sekov.' Citing United States v. Research Laboratories, Inc. (U. S. C. A. Ninth decided February 24, 1942, — Fed. (2d) —), Claimant says that such booklets under Section 201 (m) of the Act (Section 321 (m), Title 21, U. S. C. A.) must be considered as part of the label. Citing United States v. 59 Tubes, 32 Fed Supp. 960, the Government combats this view. Which is right, I do not find it necessary to decide, because the booklets, if construed as part of the label, do not help Claimant, but support the Government's contention. The front outside cover of the booklets introduces 'Sekov' as 'A path to SLENDERNESS' and shows the same picture of a slender woman shown on the container. It is then said, 'A Reducing Formula,' 'No Rigid Diet,' 'No Strenuous Exercises.' The back outside cover and the inside of the booklets contain similar statements, also two pictures of a very stout woman and a very slender woman, purporting to show 'before' and 'after' use of 'Sekov.' They also contain four strong testimonials from women, praising 'Sekov' as a flesh reducer, one claims the writer was reduced from 212 to 128 pounds, another from 149 to 130 pounds, another from 164½ to 135 pounds, and still another from 145 to 123 pounds. There are some rather obscure statements in the booklets that 'Sekov' contains thyroid and is a treatment for obesity only when used by persons suffering from hypothyroidism (lack of thyroid), but the booklets, considered as a whole, strongly affirm 'Sekov' is a reducer and a cure for obesity generally.

"Whether the label on the container is considered alone or in connection with the booklets, it is false and misleading within the meaning of the Act.

"Standing on George H. Lee & Co., v. Federal Trade Commission, 113 Fed. (2d) 583, Claimant says the order of the Federal Trade Commission renders it immune here. The Government combats this view. I find it unnecessary to decide the question thus raised, because a fair construction of the Order of the Commission [1] and the Findings of Fact and Conclusions of Law therein supports the contention of the Government, and the finding here that the labeling is false and misleading.

"2:—The Government, in its Libel, also complains with respect to such articles as follows: 'Said article is further misbranded in that it is dangerous to health when used in the dosage, or with the frequence or duration prescribed, recommended or suggested in the labeling thereof, namely, (on the carton): '30-No. 1 Capsules THIRTY DAYS SUPPLY * * * No. 1 One Capsule before Noon Meal.' This allegation is based on the fact that the capsules when taken in accordance with the suggested directions will supply a dangerous amount of thyroid.'

"This complaint is bottomed on that part of the Act reading as follows (Section 352(j), Title 21, U. S. C. A.):—'A drug or device shall be deemed to be misbranded: * * * (j) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'

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[1] A part of the Order of the Commission is as follows: "The aforesaid statements, claims, and representations used and disseminated by the respondents in the manner above described are grossly exaggerated, misleading and untrue. In truth and in fact, said preparation advertised and known as "SEKOV REDUCER" and as "SEKOV" is not a scientific treatment for obesity when administered without a thorough medical examination and without scientific care and observation, and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. Obesity may be due to several causes, including the dysfunctioning of the pituitary gland and to excess intake of food, in which cases the use of said preparation will be improper and ineffective. Said preparation will not guard the health of the user and does not act on a corrective principle for the reason that the effect of the intake of thyroid accelerates the rate of metabolism whereby the tissues, especially fatty tissues, are burned more rapidly than is normal, and such a process may be dangerous and may be injurious to the health and life of the user unless the extent of such process is carefully coordinated to the exact needs of the person suffering from hypothyroidism. The use of said preparation is a harsh or strenuous method of reducing for the reasons herein set forth. Said preparation does contain cathartics and dangerous drugs in that Capsule No. 1 of said preparation contains rhubarb, cascara sagrada, aloin and bile salts, all of which are cathartics, and all of which tend to dehydrate the body tissues. In addition said preparation contains the dangerous drug, extract of thyroid. Said preparation is not made for reaching the glands or nourishing the glands whose faulty function is the cause of most overweight. The only gland substances in said preparation are whole ovarian substance, whole pituitary substance and thyroid substance, and the effect of thyroid gland substance is to supply thyroxin to the system but not to rejuvenate the thyroid gland. Said preparation does not regulate the action of the glands gently and gradually or at all. The use of said preparation, although it may result in taking off fat by accelerating the rate of metabolism, may seriously weaken the body and the organs of the body, including the heart. Said preparation is not effective in reducing practically all cases of overweight for the reason that the drug extract of thyroid is effective only in treatment of obesity in cases in which the patient is suffering from hypothyroidism. Most overweight is caused by excessive intake of food. Said preparation does not accomplish reduction of weight or fat by normalizing the body."

"The dosage and directions for taking 'Sekov' are found on the container or cover of the package. On the outside of the container, there are these directions:—'(30-No. 1 Capsules) Thirty Days Supply (15 No. 2 Capsules) Price $5.50 Adequate directions for use on inside cover of package.'

"On the inside of the package or container, there are found these directions:—'No. 1 One Capsule before Noon Meal (Preferably half to one hour before) Not to be used by persons suffering from hyperthyroidism. No. 2 One Capsule Every Other Night (Just before retiring) Important not to be used when abdominal pain (stomach ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present.'

"The evidence supports and compels a finding and I find, that 'Sekov' is dangerous to health when used in the dosage or with the frequency or duration prescribed in the quoted directions on the label, and this is true whether the patient is or is not suffering from hyperthyroidism or from hypothyroidism.

"In the hereinbefore mentioned booklets which Claimant says must be considered as a part of the directions, it is said:—'Sekov contains Thyroid and constitutes a treatment for obesity only when used by persons suffering from hypothyroidism. (Lack of Thyroid) We recommend that you consult physician to determine the cause of your overweight as the use of Thyroid by a person not deficient in Thyroid may result in serious or irreparable injury to the health of the user.'

"If, as Claimant contends, the booklets must be looked to as part of the label, there is no change in the findings. I do not think Claimant's case is helped when the booklets are considered as a whole.

"The question arises again as to the effect here of the Order of the Federal Trade Commission in evidence and upon which Claimant relies upon for immunity. The Order contains findings that 'Sekov' is not a scientific treatment for obesity as claimed, when administered without a thorough medical examination and without scientific care and observation of the patient, and that it constitutes a treatment for obesity at all only when used by persons suffering from hypothyroidism. And that it may be dangerous and may be injurious to the health and life of the patient unless carefully coordinated to the exact needs of the person suffering from hypothyroidism. If, as Claimant insists, this Court is bound by such Findings, Claimant's case is not helped.

"It is not necessary to discuss other questions raised by the pleadings. From what has been said, it follows that the Government is entitled to Judgment, condemning such articles."

On May 28, 1942, judgment of condemnation was entered. The case was appealed to the Circuit Court of Appeals for the Fifth Circuit, and on December 8, 1943, the judgment of the District Court was affirmed, the court handing down the following opinion:

McCORD, *Circuit Judge:*

"The appeal is from a judgment condemning fifteen cartons of Sekov Reducer, an alleged remedy for obesity. The trial court found that the product had been falsely labeled and misbranded and shipped in interstate commerce contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. Par. 301 et seq., par. 334, par. 352 (a), (f) and (j). The findings of fact and conclusions of law of the trial court are included in a published opinion, United States v. fifteen Cartons, more or less, of Sekov Reducer, D. C. F. Supp. 52.

"The Sekov Reducer containers bore a picture of a woman with a slender figure. Printed booklets intended for distribution with the product were titled "Sekov, A Path to Slenderness." The labels on the packages, and the booklets which appellant alleges were distributed to purchasers, were false and misleading in that they represented Sekov Reducer to be a safe and appropriate treatment for the reduction of weight.

"Properly admitted testimony of practicing physicians clearly establishes that Sekov Reducer is not a remedy for obesity; that it will not, as claimed, reduce the figure of a stout woman to the slender proportions shown in the picture on the container; that directions for use of the product were inadequate; and that its use is dangerous to health when used with the frequency or duration prescribed in the directions on the label, 'and this is true whether the patient is or is not suffering from hyperthyroidism of from hypothyroidism.'

"(1) Appellant Sekov Corporation contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government's libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District

Court to condemn the misbranded articles was not impaired or diminished by the former proceeding. United States v. Research Laboratories, 9 Cir., 126 F. 2d 42, 45.

"(2) The findings of the District Court are supported by the evidence and its judgment is in accordance with the applicable law.

"The judgment is affirmed."

On January 27, 1943, the case instituted in the District of Nevada and the other action at Houston, Tex., having been consolidated and removed to the District Court for the Northern District of California, and the claim and answer of the Sekov Corporation having been withdrawn, judgments of condemnation and forfeiture were entered and it was ordered that the clerk return the files to the respective districts, together with copies of the decrees of condemnation, forfeiture, and destruction, in order that the marshals for those districts might destroy the product. In April 1944, a decree was entered ordering that the product at Houston, Tex., be destroyed.

1003. Adulteration and misbranding of Nelson's Antacid Powder and misbranding of B-M Cold Caps and Fero-Tona. U. S. v. 30½ Dozen Vials of B-M Cold Caps, 12½ Dozen Bottles of Fero-Tona, and 17 Packages of Nelson's Antacid Powder. Default decrees of condemnation and destruction. (F. D. C. No. 9593. Sample Nos. 6597-F to 6599-F, incl.)

On March 22, 1943, the United States attorney for the Eastern District of Missouri filed libels against 30½ dozen vials of B-M Cold Caps, 12½ dozen bottles of Fero-Tona, and 17 packages of Nelson's Antacid Powder at St. Louis, Mo., alleging that the articles had been shipped in interstate commerce, from Cleveland, Ohio, by the Great Lakes Laboratories, on or about May 25 and November 6, 1942, and January 2, 1943; and charging that they were misbranded and that the Antacid Powder was also adulterated. The Cold Caps and the Fero-Tona were labeled in part: "Distributed by Ber-Mel [or "Mels"], Inc. Cleveland, Ohio."

Examination of the Cold Caps showed that they consisted essentially of acetanilid 1.72 grains and aspirin 4.47 grains per capsule, together with caffein, laxative plant drugs, including aloin, capsicum, and alkaloids extracted from belladonna. The product was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "One capsule every 2 or 3 hours with a glassful or more of water," since, when taken in such manner, it supplied a quantity of acetanilid which was dangerous to health; (2) in that the statement in its labeling, "For Temporary Relief of Minor Colds, Flu," was false and misleading since it would not afford temporary relief from flu or all the symptoms of minor colds; (3) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of atropine, hyoscine, or hyoscyamine contained therein; (4) in that its labeling failed to bear adequate directions for use, since the directions which appeared upon the label provided for the administration of excessive amounts of acetanilid, and were therefore not adequate; and (5) in that its labeling failed to warn that frequent and continued use of a preparation containing acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence upon drugs, that frequent or continued use of a preparation containing belladonna alkaloids should be avoided, that the article was to be used cautiously if dryness of the throat occurred, and its use discontinued if rapid pulse or blurring of vision occurred, and that frequent or continued use of a laxative might result in dependence on laxatives.

Examination of the Fero-Tona showed that it consisted essentially of hexamethylenamine, potassium iodide, ferric chloride, laxative plant drugs, and strychnine sulfate. The bottle was contained in a carton much larger than necessary, since the bottle was surrounded by a liner occupying 11.8 percent of the volume of the carton, and there was 1½ inch head space above the bottle. It was alleged to be misbranded (1) in that the statements appearing in its labeling which represented and suggested that it was effective as a diuretic and was effective to aid important organs of the body to function properly were false and misleading since the article was not so effective; (2) in that its labeling failed to bear adequate directions for use, since the directions which appeared in the labeling provided for the continuous administration of a laxative and recommended for children the use of a preparation containing strychnine, and were therefore not adequate; and (3) in that its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, that frequent or contained use might result in dependence upon